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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0359]

Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for the year 2000. As part of its annual planning, budgeting, and resource allocation process, CFSAN is conducting a comprehensive review of its programs to set priorities and establish work product expectations. This notice is being published to give the public an opportunity to provide input into the priority-setting process.

DATES: Written comments by September 30, 1999.

ADDRESSES: Submit written comments concerning this document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donald J. Carrington, Center for Food Safety and Applied Nutrition (HFS-666), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-5290, email DCarring@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

CF 99152

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I. Background

On January 25, 1999, CFSAN released a document entitled “1999 CFSAN Program Priorities.” The document, a copy of which is available on CFSAN’s web page (www.cfsan.fda.com), constitutes the Center’s priority workplan for calendar year 1999. The workplan is based on input we received at a stakeholders meeting on June 24 and 25, 1998 (see 63 FR 30242, June 3, 1998), as well as input generated internally. Throughout the priority-setting process, we focused on one central question: “Where do we do the most good for consumers?”

Approximately half of the 1999 workplan consists of activities implementing the President’s Food Safety Initiative (FSI). This is consistent with the fact that currently, approximately half the Center’s resources are devoted to FSI work (i.e., all activities related to pathogen reduction in food.) Outside of FSI, the workplan identifies five program areas and four cross-cutting areas that need emphasis. The five program areas are: (1) Premarket review of food ingredients; (2) nutrition, health claims, and labeling; (3) dietary supplements; (4) chemical and other contaminants; and (5) cosmetics.

The four cross cutting areas are: (1) Enhancing the science base; (2) Federal/State/local collaborations; (3) international; and (4) human resources.

Within most major program areas in the workplan, there are two lists of activities. The first list of priorities in each section, identified as the “A” list, are activities that CFSAN is committing to complete by the end of 1999. Activities on the “B” list are those the Center plans to make progress on during the year, but may not complete. CFSAN has responsibility for many important ongoing activities that are not identified in the workplan. The workplan addresses primarily those initiatives representing something new or different that needs to be addressed in that year. In addition, the workplan does not address the myriad of unanticipated issues which often require a substantial investment of CFSAN resources e.g., recent concerns about potential dioxin-contamination in certain European imports.

II. 2000 CFSAN Program Priorities

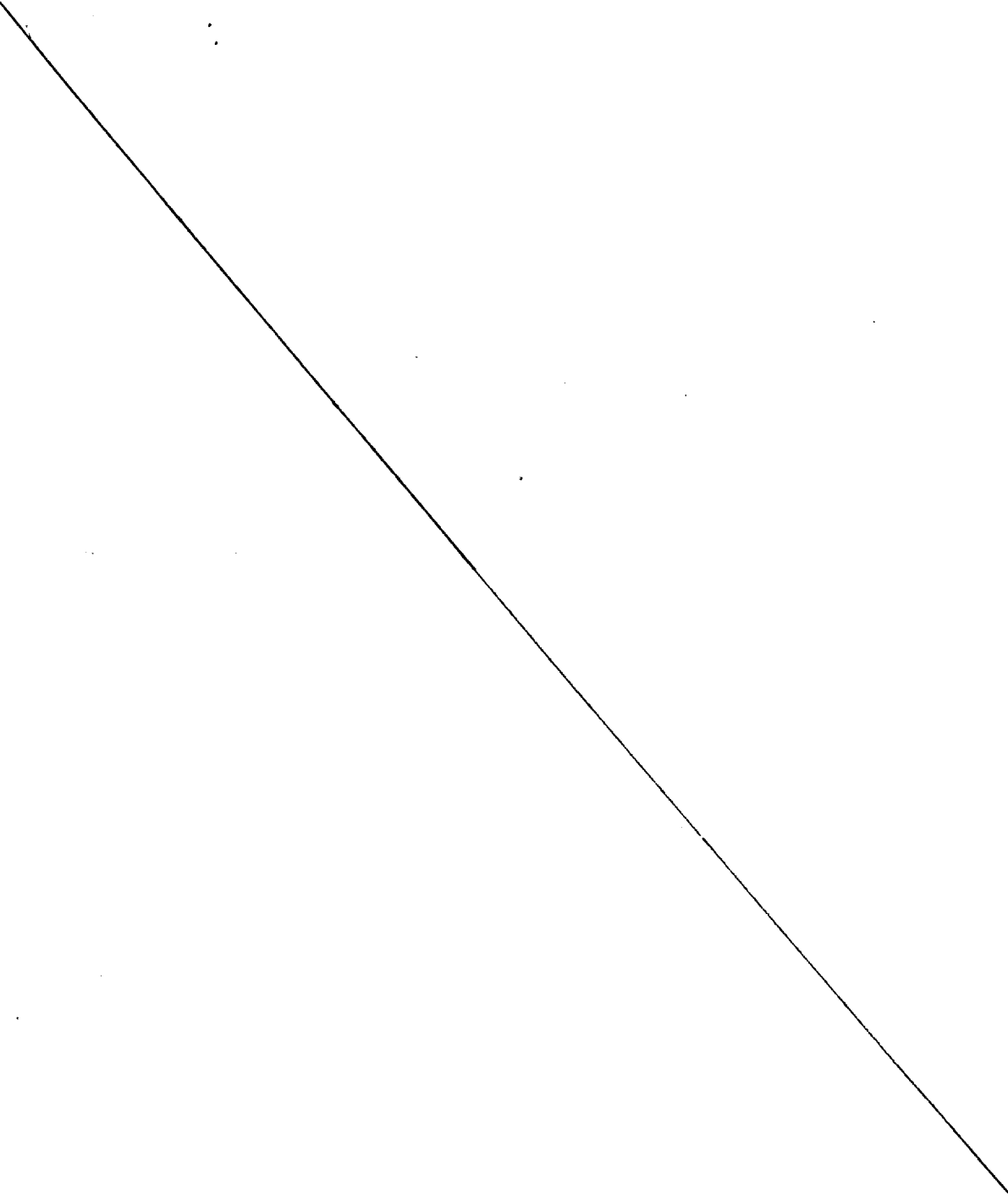
FDA is requesting comments concerning the establishment of program priorities in CFSAN for the year 2000. The input will be used to develop CFSAN's 2000 workplan. The workplan will set forth the Center's program priorities for a 9-month period, from January 1, 2000, through September 30, 2000, the end of the fiscal year. Henceforth, to be compatible with the Federal budgetary cycle, the priority-setting process and development of annual workplans will be done on a fiscal year basis. FDA intends to make this new workplan public in January 2000.

The 2000 workplan will be organized in the same format as the 1999 workplan. Accordingly, comments are requested on specific program activities for CFSAN to complete by September 30, 2000, in each of the categories described in the document entitled "1999 CFSAN Program Priorities" (i.e., "A" list activities.) Comments are also requested on those additional activities that should be worked on during the 9-month period, but not necessarily completed by the end of the fiscal year (i.e., the "B" list activities.)

To help focus comments, FDA requests that input regarding CFSAN program priorities address the following questions:

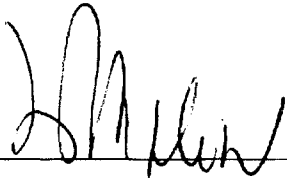
1. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?
2. Within the 10 program areas identified previously, what specific activities do you believe should be top priorities for CFSAN and why?
3. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?
4. Because so much of our nation's food supply is either imported or exported, what do you believe should be the highest priority international activities? Please identify specific activities in your answer.

Interested persons may, on or before September 30, 1999, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with



the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/25/99
August 25, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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